

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 002441.00195	<b>FOR FURTHER ACTION</b>		See item 4 below
International application No. PCT/US2006/018411	International filing date ( <i>day/month/year</i> ) 12 May 2006 (12.05.2006)	Priority date ( <i>day/month/year</i> ) 13 May 2005 (13.05.2005)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant NOVARTIS VACCINES AND DIAGNOSTICS, INC.			

<p>1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i>.1(a).</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.</p>																								
<p>3. This report contains indications relating to the following items:</p> <table> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> <p>4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44<i>bis</i>.3(c) and 93<i>bis</i>.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44<i>bis</i> .2).</p>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input checked="" type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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<input type="checkbox"/>	Box No. VIII	Certain observations on the international application																						

	Date of issuance of this report 14 November 2007 (14.11.2007)
<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. +41 22 338 82 70</p>	<p>Authorized officer</p> <p><b>Athina Nickitas-Etienne</b></p> <p>e-mail: pt04.pct@wipo.int</p>

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

## PCT

To:

see form PCT/ISA/220

### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/US2006/018411

International filing date (day/month/year)  
12.05.2006

Priority date (day/month/year)  
13.05.2005

International Patent Classification (IPC) or both national classification and IPC  
INV. C07K14/315

Applicant  
NOVARTIS VACCINES AND DIAGNOSTICS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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Tel. +49 89 2399 - 0 Tx: 523656 epmu d  
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Date of completion of  
this opinion

see form  
PCT/ISA/210

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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2006/018411

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of:
  - ☒ the international application in the language in which it was filed
  - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☒ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ on paper
    - ☒ in electronic form
  - c. time of filing/furnishing:
    - ☒ contained in the international application as filed.
    - ☒ filed together with the international application in electronic form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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**Box No. II Priority**

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1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2006/018411

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 35, 56

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for the whole application or for said claims Nos. 35, 56

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13~~ter~~.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2006/018411

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	<u>1-24, 28-59</u>
	No: Claims	<u>25-27</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-59</u>
Industrial applicability (IA)	Yes: Claims	<u>1-34, 36-55, 57-59</u>
	No: Claims	

2. Citations and explanations

see separate sheet



**Prior Art.**

- The documents mentioned in this search opinion are numbered as in the search report, i.e. D1 corresponds to the first document of the search report.

**Novelty (Art. 33(1,2) PCT)**

1. The present application discloses portions of a known protein (here called bibA protein). The full-length amino acid and nucleotide sequence of bibA is disclosed in D1 (see SEQ Nos 6265, 6266, 8957, 8958), D2 and D3 (sequence SAG2063).
2. Claims 25-27 are directed to a nucleic acid molecule which encodes a bibA polypeptide or comprises the nucleic acid sequence of SEQ ID NO: 16.
3. Since nucleic acid molecules encoding bibA or comprising SEQ ID NO. 16 are disclosed in D1, D2 and D3, the subject matter of these claims is not considered new, Art. 33(2) PCT and the requirements of Art. 33(1) PCT are not satisfied in respect of novelty for this claim.
4. Portions of the bibA protein are not disclosed in the prior art. The subject matter of **claims 1-24, 28-59 is therefore new** with respect to the prior art and the claims satisfy the requirements of Art. 33(1) PCT with respect to novelty.

**Inventive Step (Art. 33(1,3) PCT.**

1. The present set of claims is directed to portions of a known protein (bibA).
2. However, fragments of Streptococcus proteins are disclosed in D1 (see p. 2-3) where it is mentioned, "the invention further provides proteins comprising fragments of the S. agalactiae amino acid sequences disclosed in the examples, and proteins comprising fragments of the S. pyogenes amino acid sequences disclosed in the examples... Preferably the fragments comprise one or more epitopes from the sequence. Other preferred fragments are (a) the N-terminal signal peptides of the proteins disclosed in the examples, (b) the proteins disclosed in the examples, but

without their N-terminal signal peptides, © fragments common to the related GAS and GBS proteins disclosed in the examples, and (d) the proteins disclosed in the examples, but without their N-terminal amino acid residue.." (D1 p. 2). D4 discloses Streptococcus agalactiae protein sequences and fragments thereof (see p. 9-11 and sequence 2967). D5 discloses isolated nucleic acid molecules encoding a hyperimmune serum reactive antigen or a fragment thereof as well as hyperimmune serum reactive antigens or fragments thereof from S. agalactiae (see abstract). D5 also discloses a sequence (364) which is 90% identical to SEQ ID NO. 1 of the present application.

3. The ISA considers that the provision of portions of a known protein does not involve an inventive step especially since the possibility of producing fragments or immune reactive antigens for producing vaccines is disclosed in D1, D4 or D5. The ISA is of the opinion that, in the light of the available prior art, claims 1-59 of the application lack an inventive step as defined in Art.33(3) PCT.

#### **Clarity (Art. 6 PCT)**

- Claims 23 and 28 do not fulfil the clarity requirements of Art. 6 PCT, because the terms "GBS1-GBS689" seem to be internal designations of proteins which would not be understandable to the person skilled in the art.

#### **Further comments:**

For the assessment of the presently worded claims 35 and 56 on the question whether they are industrially applicable no unified criteria exist in the PCT. The patentability can also be dependent upon the formulation of the claims. The EPC, for example, does not recognise as industrially applicable claims to the use of a compound in medical treatment, but will allow however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.